



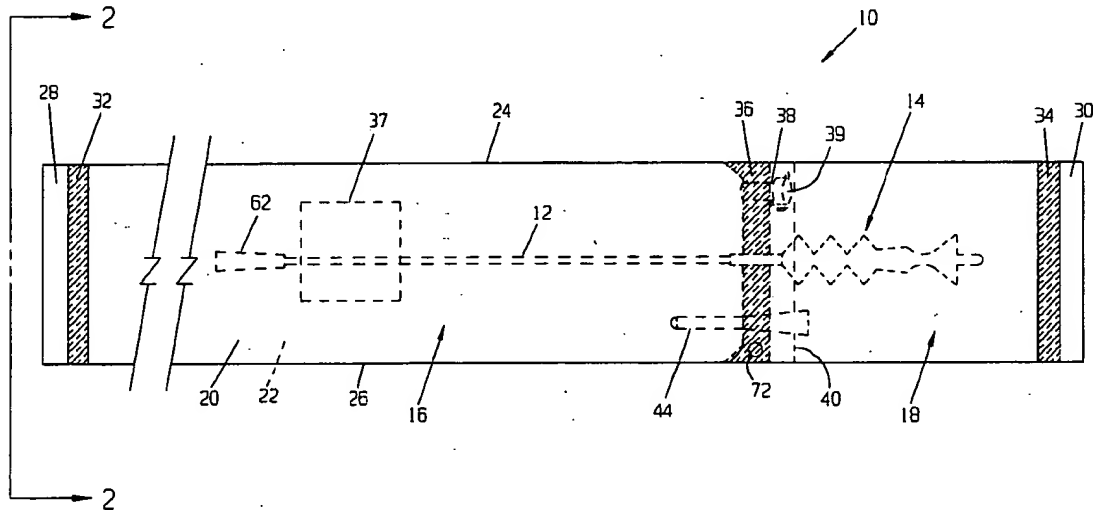
US005454798A

**United States Patent** [19][11] **Patent Number:** **5,454,798****Kubalak et al.**[45] **Date of Patent:** **Oct. 3, 1995**[54] **DISPOSABLE URINE BAG**4,230,115 10/1980 Walz et al. .... 604/349  
5,147,341 9/1992 Starke et al. .... 604/349[75] **Inventors:** **Thomas P. Kubalak**, Plymouth; **Daniel P. Welch**, Zimmerman, both of Minn.; **Daniel J. Habecker**, Santa Barbara, Calif.*Primary Examiner*—Randall L. Green  
*Assistant Examiner*—Rob Clarke  
*Attorney, Agent, or Firm*—Hugh D. Jaeger[73] **Assignee:** **Mentor Corporation**, Minneapolis, Minn.[21] **Appl. No.:** **61,901**[22] **Filed:** **May 14, 1993**[51] **Int. Cl.<sup>6</sup>** ..... **A61F 5/44**[52] **U.S. Cl.** ..... **604/328; 604/349; 604/326;**  
128/761[58] **Field of Search** ..... 128/761, 768;  
604/326-331, 346-353, 4/144.1-144.4[57] **ABSTRACT**

A disposable urine bag having sealed cavity members where one cavity stores an extendable catheter and also acts as a urine storage reservoir. A second sealed and peel-away cavity includes a catheter advancement mechanism which provides for lubricated catheter advancement without actual contact of the catheter by the human hand. An absorption member is provided to semi-solidify urine stored in the urine storage reservoir.

[56] **References Cited****U.S. PATENT DOCUMENTS**

4,204,527 5/1980 Wu et al. .... 604/349

**31 Claims, 6 Drawing Sheets**

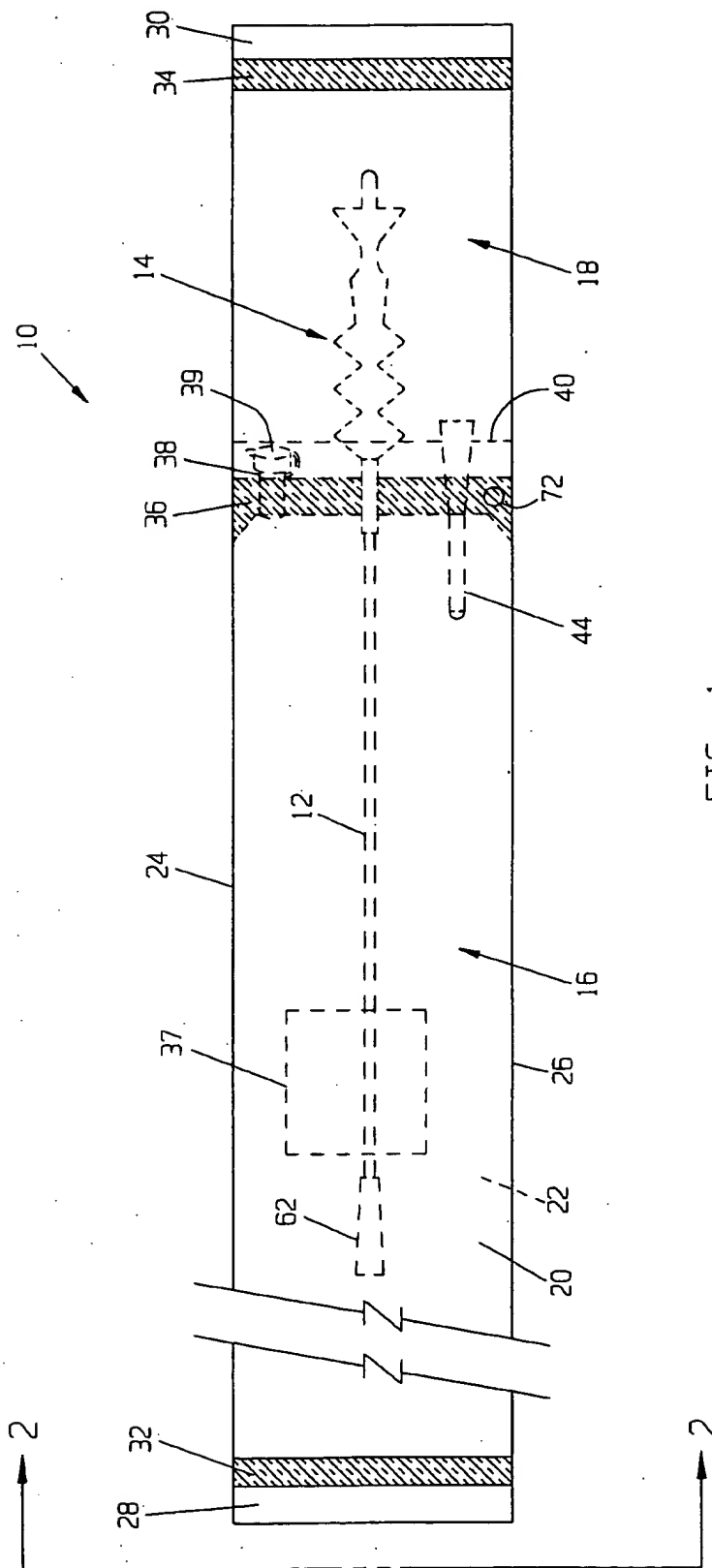


FIG. 1

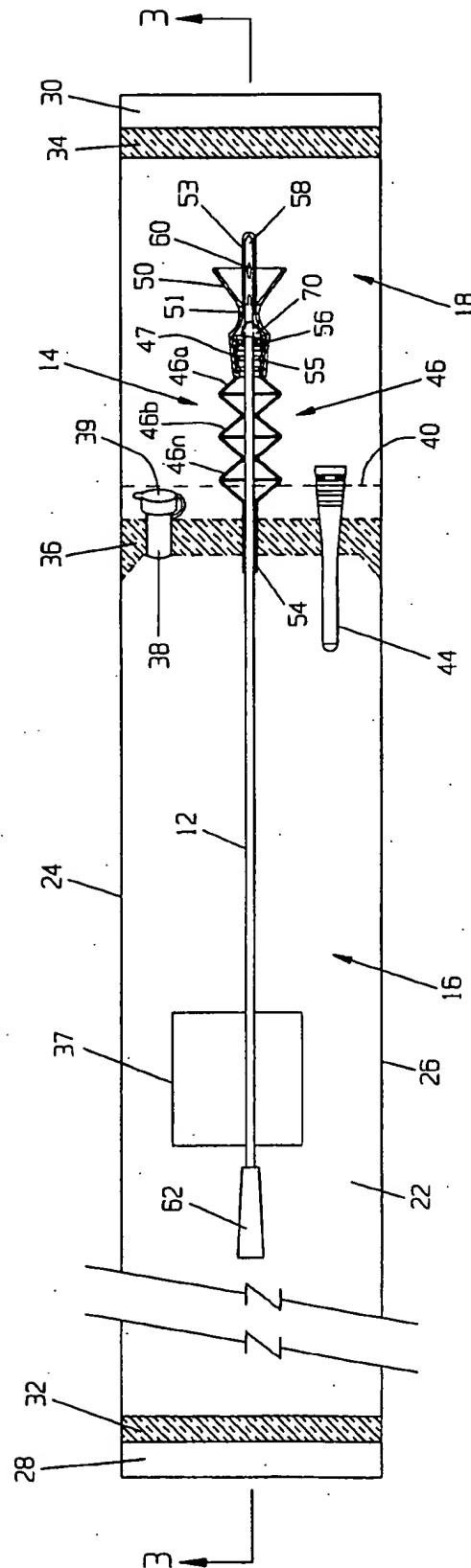


FIG. 2

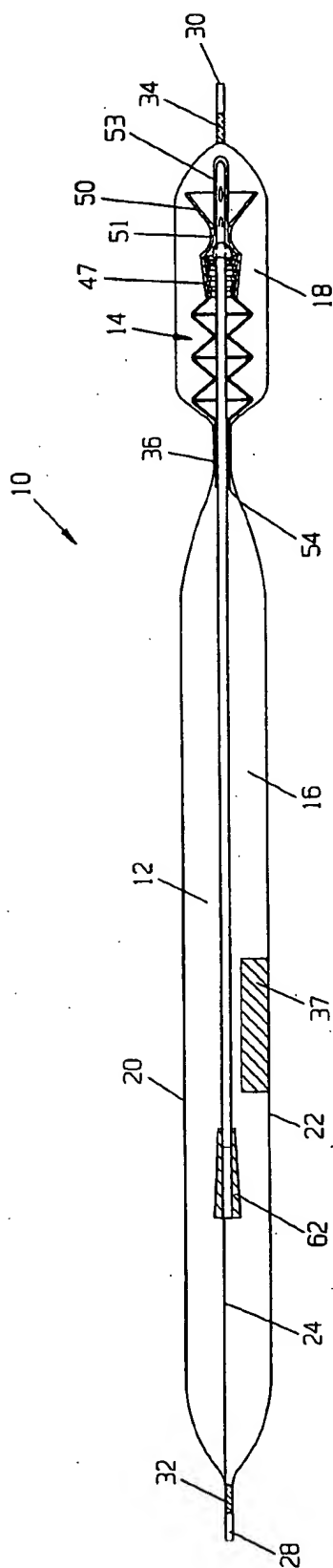


FIG. 3

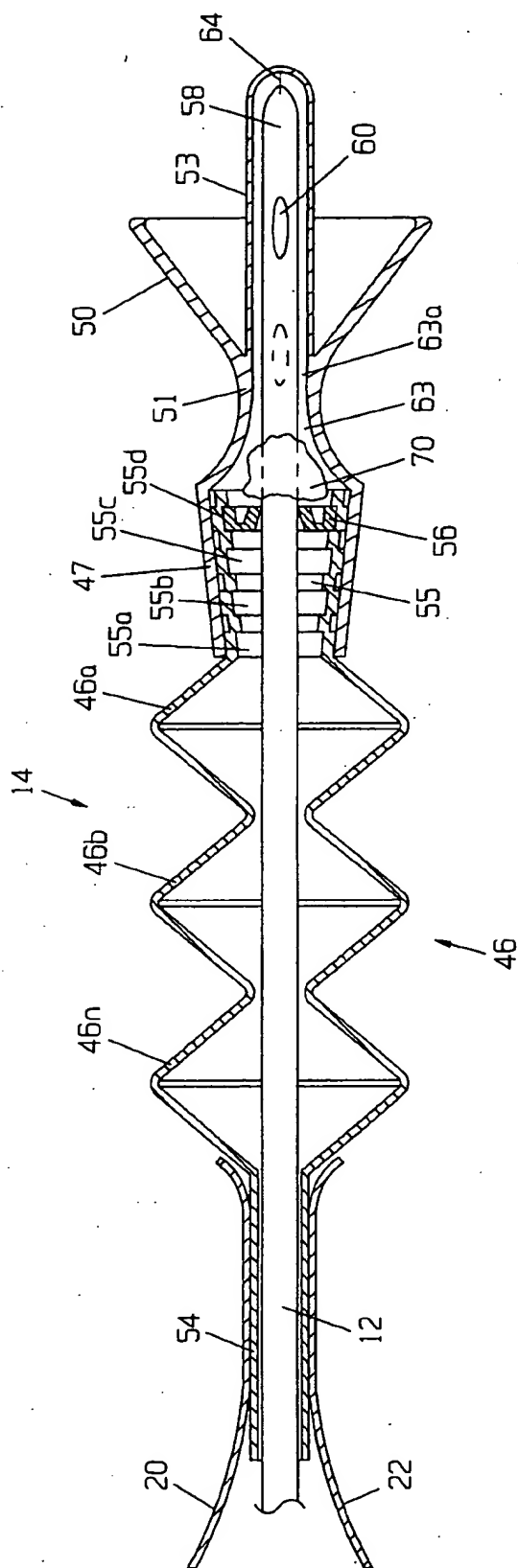


FIG. 4

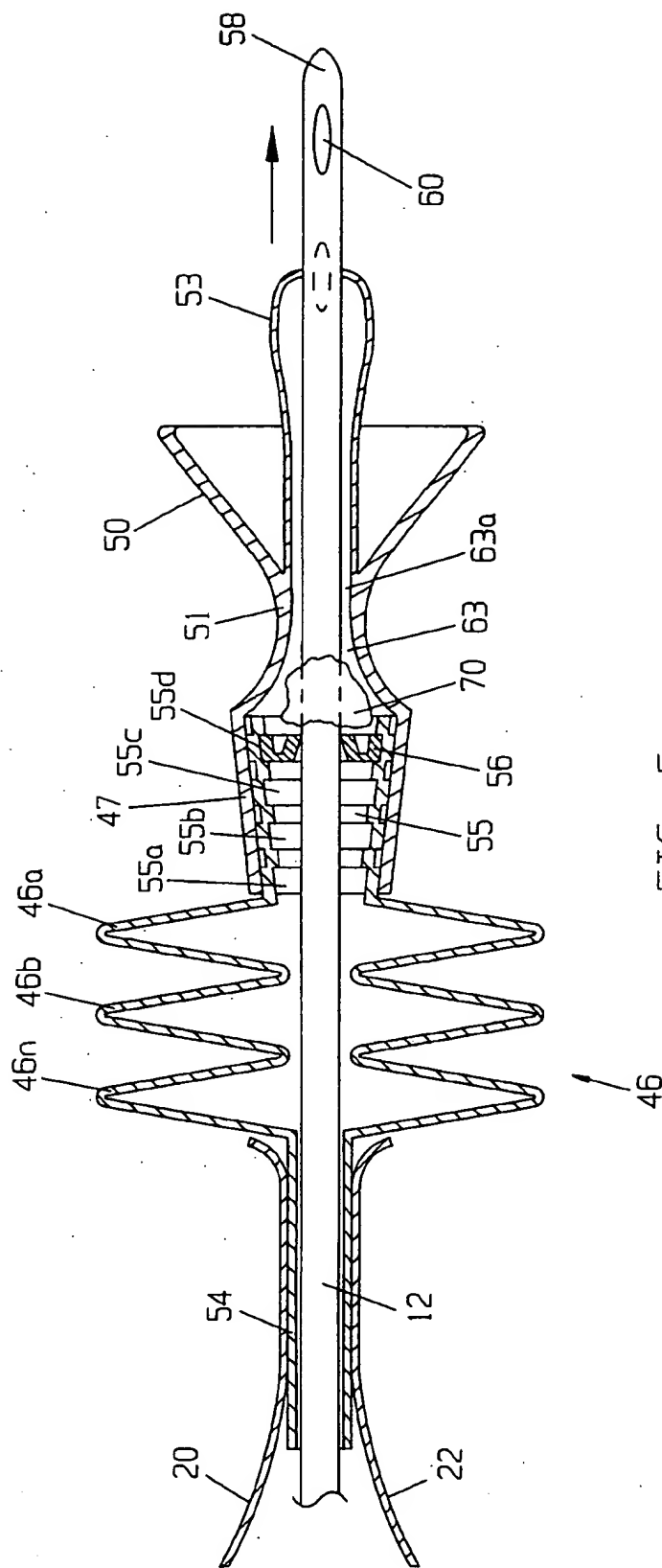


FIG. 5

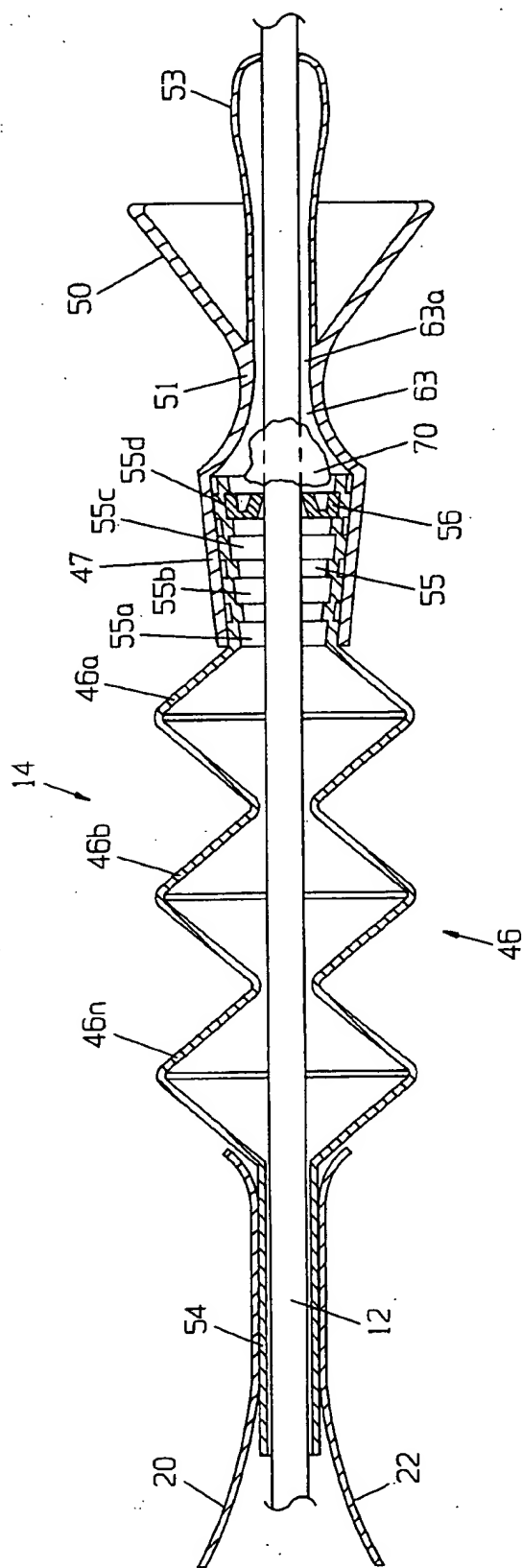


FIG. 6

## DISPOSABLE URINE BAG

## CROSS REFERENCES TO CO-PENDING APPLICATIONS

This patent application relates to U.S. patent application Ser. No. 07/989,517, filed Dec. 11, 1992, entitled "Disposable Urine Bag", and to the same assignee as the present patent application.

## BACKGROUND OF THE INVENTION

## 1. Field of the Invention

The present invention pertains to a bodily waste collector bag, and more particularly, pertains to a disposable urine bag and a process for extending an extendable catheter disposed from the interior of the urine bag.

## 2. Description of the Prior Art

Prior art urine bags have a multiplicity of members constructed in a fashion where the catheter is an external device which must be attached to the urine bag. Other prior art urine bags have required a great deal of dexterity to manipulate the catheter from out of the bag. Accidental touching of the catheter could result in contamination of the sterile surface of the catheter. Subsequent to urine disposition within the bag, the urine bag required sealing by a cap or other device to contain the urine within the urine bag. Disposing of some of the prior art urine bags created a problem in that a bag and a catheter, as separate units, had to be disposed of carefully. Prior art urine bags could also be accidentally punctured prior to disposal, thus creating an undesirable fluid leakage around and about the urine bag and the person.

The present invention overcomes the problems of the prior art urine bag devices by providing a single unit, disposable urine bag having a self-contained, extendable catheter and having a urine absorbing chemical or mechanism within the urine bag.

## SUMMARY OF THE INVENTION

The general purpose of the present invention is to provide a single unit disposable urine bag having a self-contained and stored extendable catheter with an advancement mechanism, which is a part of the urine bag. A highly absorbent chemical stored in the urine bag cavity reacts with urine to produce a semi-solid like mass within the confines of the urine bag, thus alleviating spillage of urine from the urine bag. Alternatively, a drain is incorporated to drain urine from the interior of the urine bag cavity, such as for testing of the urine or disposal of the urine.

According to one embodiment of the present invention, there is provided a flexible disposable urine bag having one or more cavities formed between joined flexible top and bottom plastic members. Formable and sealable pockets or cavities are formed by electronic, RF, ultrasonic, induction, thermal adhesive or other suitable welds between the flexible top and bottom flexible polymer members. An advancement mechanism is secured within one sealed and detachable cavity of the collection device with its majority structure extending from the sealed edge of a sealed reservoir or cavity area containing an advanceable catheter. The advancement mechanism can also lubricate and slidably seals the catheter to prevent leakage of urine from the sealed cavity reservoir, and also allows for easy passage of the catheter out of the reservoir without contact with human

hands. The stored catheter, having a conical-shaped rubber or rigid polymer stop member is positioned in alignment with a sealable advancement mechanism for subsequent extension therethrough. A perforation separates the urine bag cavities from each other which is used for an aseptic presentation of the catheter advancement mechanism and the catheter.

One significant aspect and feature of the present invention is a disposable urine bag having a self-stored and contained extendable catheter with an advancing mechanism for a non-contact, easy to use device, having a lubricant reservoir within the advancement mechanism. The advancement mechanism for the urine bag includes a seal which mates with an extendable catheter.

Another significant aspect and feature of the present invention is a perforated tear seam between upper and lower flexible top and bottom bag members forming the cavities.

Still another significant aspect and feature of the present invention is the use of a highly absorbent chemical which combines with the urine or fluid to form a non-leaking, semi-solid mass within the disposable urine bag. While the specification is directed towards urine, the teachings of the present invention can be extended to any type of fluid.

Having thus described embodiments of the present invention, it is one object of the present invention to provide a single-unit disposable urine bag having a self-contained catheter with an advancing mechanism, chemical absorbent, and cavity drain.

## BRIEF DESCRIPTION OF THE DRAWINGS

Other objects of the present invention and many of the attendant advantages of the present invention will be readily appreciated as the same becomes better understood by reference to the following detailed description when considered in connection with the accompanying drawings, in which like reference numerals designate like parts throughout the figures thereof and wherein:

FIG. 1 illustrates a top view of the urine bag having a self-contained catheter and catheter advancement mechanism;

FIG. 2 illustrates a top view in horizontal cross section of the urine bag along line 2—2 of FIG. 1;

FIG. 3 illustrates a side view in cross section of the urine bag along line 3—3 of FIG. 2;

FIG. 4 illustrates a cross-sectional view of the catheter advancement mechanism prior to catheter advancement;

FIG. 5 illustrates the first advancement of the catheter and compression of the bellows mechanism subsequent to removal of the right cavity half; and,

FIG. 6 illustrates the bellows in the relaxed mode subsequent to a number of catheter advancements by manipulation of the catheter advancement mechanism.

## DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

FIG. 1 illustrates a top view of a urine bag 10, the present invention, including a self-contained catheter 12 and a catheter advancement mechanism 14 in the urine bag 10. The urine bag 10 is of one-piece, and separable, polymer construction having a left cavity 16 for holding urine and a detachable adjacent right cavity 18 by a tearable perforation or like seam 40 for providing an aseptic cavity for enclosing medical structures as later described in detail. The closed cavity provides for protection against skin flora, handling



and provides for an aseptic environment. The urine bag 10 is of a continuous construction and includes an essentially planar top flexible polymer member 20 and an opposing essentially planar bottom flexible polymer member 22 between edges 24 and 26. Ends 28 and 30 are suitably sealed by seals 32 and 34, such as by ultrasonic welding, gluing or other suitable processes known in the art, and are shown as being hatched to define such sealed areas. Edges 24 and 26 can also be secured, such as by welding or ultrasonic sealing or other like securing processes. Another configured welded or glued seal 36, which is also cross hatched, serves to form a barrier between the left and right cavities 16 and 18 and also to anchor the catheter advancement mechanism 14 to the left cavity 16. Cavity 18 is to facilitate the presentation of the catheter in an aseptic manner. The left cavity 16 is bounded by the top flexible polymer member 20, the bottom flexible polymer member 22, end seal 32 and seal 36. The right cavity 18 is bounded by the top flexible polymer member 20, the bottom flexible polymer member 22, the end seal 34 and the seal 36. The left cavity 16 stores the catheter 12 prior to use and is a collector and reservoir for urine. Also, a highly absorbent chemical 37, such as potassium or sodium polyacrylate, can be provided within the left cavity 16. Alternatively, a cavity drain 38 having an attached sealing cap 39 can also be included. The cavity drain 38 drains the left cavity 16, and is secured thereto by the weldment seal 36. The highly absorbent chemical 37, which can be in a pouch which dissolves with contact to water, urine or other fluid, and in granular form or other suitable form, is placed within the compartment 16. Urine or other aqueous medium is absorbed by the absorbent chemical medium 37, which expands to form a semi-solidified, gel-like material which has a putty-like consistency, thus eliminating any potential cavity leakage problems should a subsequent event such as a cavity puncture occur, or also for sanitary disposal.

The right cavity 18 houses one end of the catheter advancement mechanism 14 and includes a perforated tearable seam or a tearable seam 40, which allows the right cavity 18 to be separated from the left cavity member 16, thus exposing the distal end of the catheter advancement mechanism 14 just prior to deployment of the catheter 12 from the left cavity 16 as later described in detail. Also included is a leak-resistant small holster cavity 44 into which the distal end of the catheter 12 secures to preclude leakage of urine from the catheter 12 and left cavity 16 after urine bag usage. The holster cavity 44 secures to the left cavity 16 under the weldment seal 36. The catheter 12 includes a conical connector 62. A support hole 72 provides for securing of the urine bag to a stand or clothing of the user.

FIG. 2 illustrates a top view in horizontal cross section of the urine bag 10 generally along line 2—2 of FIG. 1 where all numerals correspond to those elements previously described. The top flexible member 20 has been removed for purpose of brevity and clarity of illustration. Weldment areas 32, 34 and 36 are illustrated in cross hatching for purposes of brevity and clarity. Illustrated in particular is the engagement of the catheter 12 with the catheter advancement mechanism 14. The two-section, soft polymer catheter advancement mechanism 14 includes, but is not limited to, a first flexible polymer portion having a soft pliable plastic conically shaped glands positioner 50, a narrow manipulation point 51, a tapered coupling 47, and an introducer 53 extending to the right of the glands positioner 50. The second flexible polymer portion includes a tapered and ringed coupler 55, a plurality of bellows members 46a—46n

and a tubular member/manipulation point 54, which is anchored to the top and bottom flexible polymer members 20 and 22 by weldment seal 36. This bellows structure can be injection molded, blow molded or dipped polymer material. The tapered coupling 47 secures by suitable bonding and frictional engagement over and about the tapered and ringed coupler 55 to form the joined flexible portions of the catheter advancement mechanism 14. The catheter 12 includes a distal tip 58, one or more ports 60 in the distal tip 58, and a conical connector 62 at its proximal end, which acts as a stop against the tubular member/manipulation point 54 to preclude removal of the catheter completely from the confines of the left cavity 16 during deployment of the catheter advancement mechanism 14. The catheter 12 slidably aligns through the tubular member/manipulation point 54, through the center of the bellows members 46a—46n, through the tapered and ringed coupler 55, through the manipulation point 51, through the glands positioner 50 and through the introducer 53 which has a double slotted end through which the distal end of the catheter 12 passes during deployment. The catheter 12 also passes through a U-cup seal 56 and lubricant 70 which are illustrated in the following figures. The catheter 12 is appropriately dimensioned to allow unrestricted passage and wiping of excessive lubricant by lumen 63 formed by the interior of the catheter advancement mechanism 14 illustrated in FIG. 4.

FIG. 3 illustrates a side view in cross section along line 3—3 of FIG. 2 of the urine bag 10 where all numerals correspond to those elements previously described. Illustrated in particular are the cavities 16 and 18 and the previously described components therein.

FIG. 4 illustrates a cross-sectional view of the catheter advancement mechanism 14 subsequent to removal of the right cavity 18 along the tear line 40 of FIG. 2 and ready for deployment of the catheter 12 where all numerals correspond to those elements previously described. The bellows 46 include bellow members 46a, 46b, and 46n, which can be a blow molded polymer. The tapered and ringed coupler 55 includes internal annular grooves 55a—55d any of which can provide for suitable nesting of a pliable U-cup seal 56, which can be of a suitable size to match the diameter of the catheter 12. Lubricant 70 is contained in a lumen 63 of the manipulation point 51 between the U-cup seal 56 and the ever narrowing lumen 63. The narrowest point 63a of the lumen 63 allows an appropriate amount of lubricant 70 to be applied to the advancing catheter 12. The tip of the introducer 53 includes two crossed slits forming an "x" to allow egress of the proximal end of the catheter 12 during deployment through the two expanded crossed slits which then separate and move outwardly.

#### MODE OF OPERATION

FIGS. 5—6 best illustrate the mode of operation including the advancement of the catheter 12 through the urine bag 10.

FIG. 5 illustrates the first advancement of the catheter 12 and compression of the bellows 46 where all numerals correspond to those elements previously described. The first advancement of the catheter 12 and compression of the bellows 46 is accomplished by manually compressing the flexible tubular member/manipulation point 54 against the catheter 12 and applying a forward force to the right, while with the other hand the glands positioner 50 is held against the gland. The introducer 53 is inserted into the meatus urethra and the catheter 12 is advanced to open and pass through the "x" slits in the end of the introducer 53.

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Continued forward force is applied to insure that the catheter 12 enters the meatus urethra. If the catheter 12 has penetrated, the flexible manipulation point 51 is squeezed with the same hand to maintain the position of catheter 12 in the meatus urethra, and pressure is manually released at the flexible tubular member/manipulation point 54. This lets bellows section 46 spring back to the position shown in FIG. 6. This sequence is repeated until full insertion of the catheter 12 is complete. As this is accomplished, the flexible tubular member/manipulation point 54 and the glands positioner 50 are also relatively re-positioned proximally with respect to the catheter 12, having previously exposed the distal tip 58 of the catheter 12.

FIG. 6 illustrates the bellows 46 in the relaxed mode subsequent to a second and required number of additional advancements of the catheter 12 through the catheter advancement mechanism 14 until the catheter 12 has advanced sufficiently through the meatus urethra for required urine drainage. Removal of the catheter 12 is accomplished by grasping and applying pressure at the manipulation point 51 and then withdrawing the catheter 12 from the meatus urethra. The distal tip 58 is then secured within the holster cavity 44, thereby sealing the catheter 12 from inadvertent spillage. The interior of the holster cavity 44 is tapered to appropriately accommodate various diameter catheters.

Various modifications can be made to the present invention without departing from the apparent scope hereof.

We claim:

1. A urine bag comprising:
  - a. two opposing polymer members forming a holding cavity means for urine and a clean cavity means for a catheter insertion means, and a seam means between said holding cavity means and said clean cavity means;
  - b. said catheter insertion means including and connected in order a bellows means connected to one end of said holding cavity means and including a glands positioner;
  - c. a catheter extending through said bellows means including a conical connector at one end for engaging with a tubular member in the end of said holding cavity means; and,
  - d. a catheter holster means to captivate and seal said catheter and urine storage means upon completion of a voiding cycle.
2. The urine bag of claim 1 including an absorbing means in said holding cavity means.
3. The urine bag of claim 1 wherein said holding cavity means includes a cavity drain means.
4. The urine bag of claim 1 wherein said holding cavity means includes a leak-resistant holster cavity means.
5. The urine bag of claim 1 wherein said holding cavity means includes a support hole means.
6. The urine bag of claim 1 including a tubular member and manipulation point means in the end of said holding cavity means.
7. The urine bag of claim 1 wherein said seam means is a tearable seam.
8. The urine bag of claim 1 wherein said seam means is a perforated tearable seam means.
9. The urine bag of claim 1 including a lubricant in said bellows means.
10. A urine bag comprising:
  - a. two opposing polymer members forming a holding cavity means for urine and a cavity means for a catheter insertion means, and a perforation means between said cavity means;
  - b. said catheter insertion means including and connected

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in order, a bellows connected to one end of said holding cavity means, a tapered and ring coupler, a manipulation point, an introducer with crossed x slits, and a glands positioner at one end of said bellows means; and,

- c. a catheter including holes, extending through said catheter insertion means and including a conical connector at one end for engaging with a tubular member.
11. The urine bag of claim 10 including a urine or fluid absorption material in said holding cavity means.
12. The urine bag of claim 10 wherein said holding cavity means includes a cavity drain means.
13. The urine bag of claim 10 wherein said holding cavity means includes a holster cavity means.
14. The urine bag of claim 10 wherein said holding cavity means includes a support hole means.
15. The urine bag of claim 10 including a tubular member and manipulation point means in the end of said holding cavity means.
16. The urine bag of claim 10 wherein said seam means is tearable seam.
17. The urine bag of claim 10 wherein said seam means is a perforated tearable seam means.
18. The urine bag of claim 10 including a lubricant on said bellow means.
19. The urine bag of claim 10 including a fluid absorption material in a disposable package in said holding cavity means.
20. The urine bag of claim 10 including a hydrogel in said holding cavity means.
21. A urine bag comprising:
  - a. two opposing polymer members forming a holding cavity means for urine and a cavity means for a catheter insertion means, and a perforation means between said cavity means;
  - b. said catheter insertion means including and connected in order, a bellows means connected to one end of said holding cavity means, a tapered and ring coupler including internal annular grooves, a manipulation point, an introducer with crossed slits, and a glands positioner at one end of said bellows means; and,
  - c. a catheter including holes extending through said catheter insertion means and including a conical connector at one end for engaging with a tubular member.
22. The urine bag of claim 21 including a urine or fluid absorption material in said holding cavity means.
23. The urine bag of claim 21 including a urine or fluid absorption material in a dissolvable package in said holding cavity means.
24. The urine bag of claim 21 wherein said holding cavity means includes a cavity drain means.
25. The urine bag of claim 21 wherein said holding cavity means includes a leak-resistant holster cavity means.
26. The urine bag of claim 21 wherein said holding cavity means includes a support hole means.
27. The urine bag of claim 21 including a tubular member and manipulation point means in the end of said holding cavity means.
28. The urine bag of claim 21 wherein said seam means is tearable seam.
29. The urine bag of claim 21 wherein said seam means is a perforated tearable seam means.
30. The urine bag of claim 21 including a lubricant in said catheter insertion means.
31. The urine bag of claim 21 wherein said bellow means is blow molded.

\* \* \* \* \*



US006053905A

**United States Patent** [19]**Daignault, Jr. et al.**[11] **Patent Number:** **6,053,905**[45] **Date of Patent:** **Apr. 25, 2000**[54] **SELF CONTAINED URETHRAL CATHETER ASSEMBLY WITH LUBRICATING CHAMBER**

5,226,530	7/1993	Golden	206/364
5,242,398	9/1993	Knoll et al.	604/544
5,454,798	10/1995	Kubalak et al.	604/328
5,501,341	3/1996	Vanes	206/364

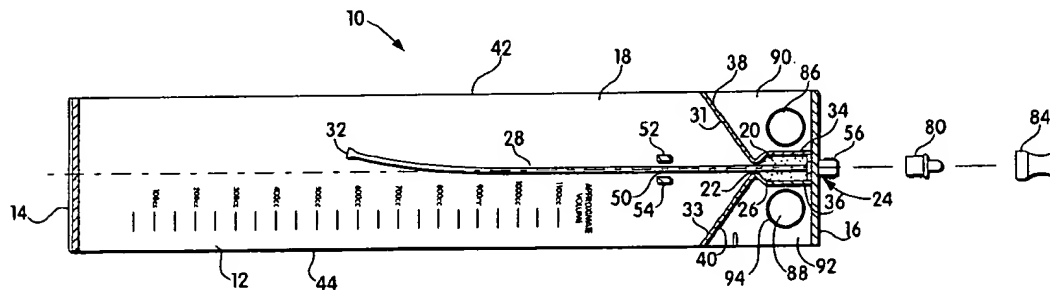
[75] **Inventors:** Kenneth J. Daignault, Jr., Jefferson;  
Donald A. Coelho, Jr., Bellingham;  
Lee C. Burnes, North Attleboro; James  
A. Walls, Sharon, all of Mass.**FOREIGN PATENT DOCUMENTS**

1493257	11/1977	United Kingdom	
94/06377	3/1994	WIPO	604/328
WO 98/06642	2/1998	WIPO	

[73] **Assignee:** Tyco International (US) Inc., Exeter,  
N.H.**Primary Examiner**—Mark O. Polutta  
**Attorney, Agent, or Firm**—Weingarten, Schurging, Gagnebin  
& Hayes LLP[21] **Appl. No.:** 09/027,678[57] **ABSTRACT**[22] **Filed:** Feb. 23, 1998[51] **Int. Cl.<sup>7</sup>** ..... A61M 27/00[52] **U.S. Cl.** ..... 604/544; 604/331; 604/349;  
206/364; 206/571[58] **Field of Search** ..... 604/265, 328,  
604/331, 349, 544; 206/364, 571[56] **References Cited****U.S. PATENT DOCUMENTS**

3,854,483	12/1974	Powers	
3,934,721	1/1976	Juster et al.	206/364
3,967,728	7/1976	Gordon et al.	206/364
4,230,115	10/1980	Walz, Jr. et al.	
4,652,259	3/1987	O'Neil	
4,811,847	3/1989	Reif et al.	206/571
5,147,341	9/1992	Starke et al.	

A self-contained, self-lubricating catheter assembly is provided. A receptacle formed of two opposed flexible walls includes a main chamber and a lubrication chamber separated by a passage. A lubricant is provided in the lubrication chamber. A catheter is advanced from the main chamber through the lubrication chamber and picks up lubricant as it passes through the lubrication chamber. A catheter grasping mechanism, located proximate the exit from the lubrication chamber, permits advancement of the catheter out of the receptacle and resists movement of the catheter back into the receptacle. The receptacle also includes one or more finger holes therethrough to allow the user to retain the receptacle on one or more fingers, thereby allowing the hand to more readily position the receptacle during use while advancing the catheter.

**38 Claims, 7 Drawing Sheets**

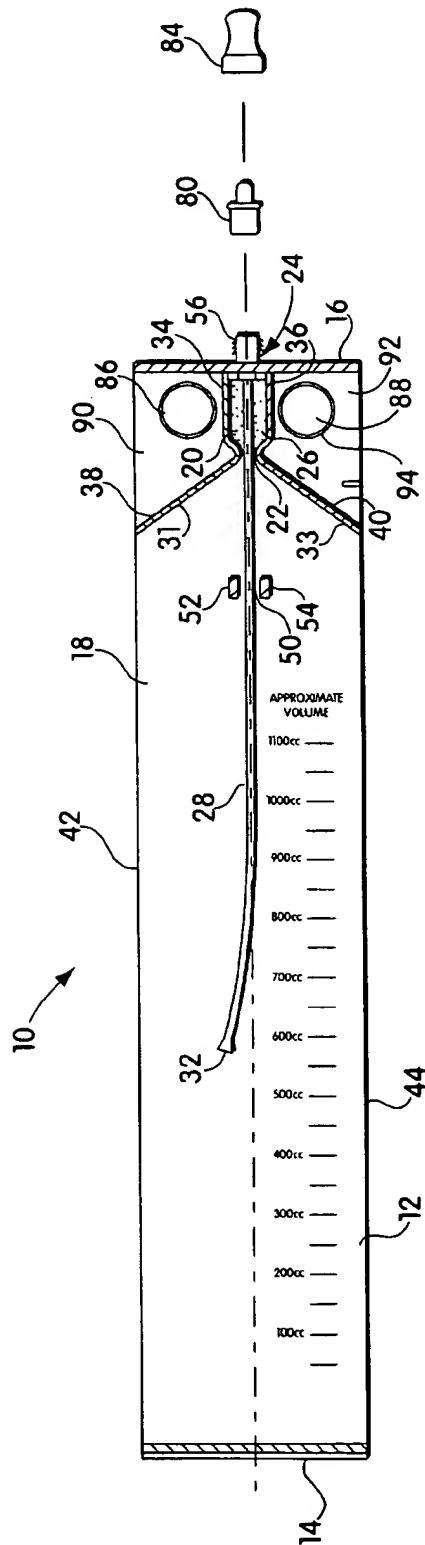


Fig. 1

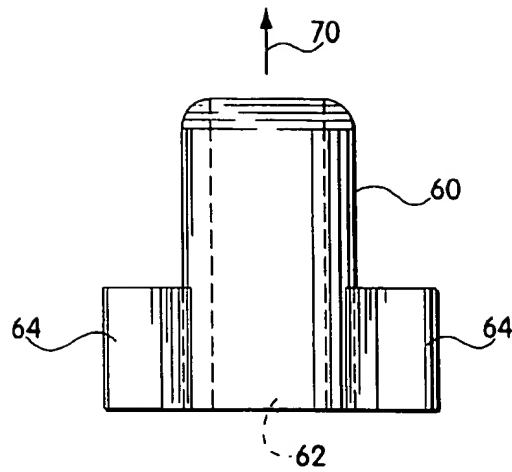


Fig. 2

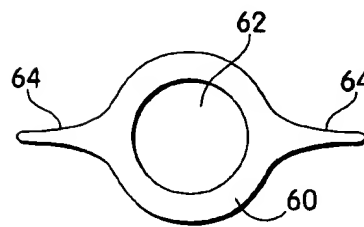


Fig. 3

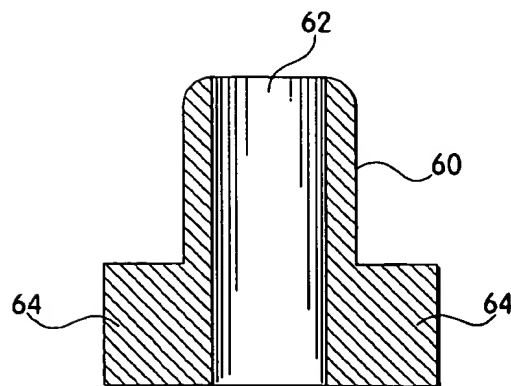


Fig. 4

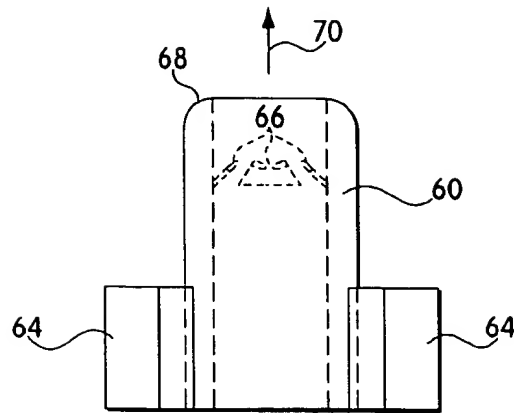


Fig. 5

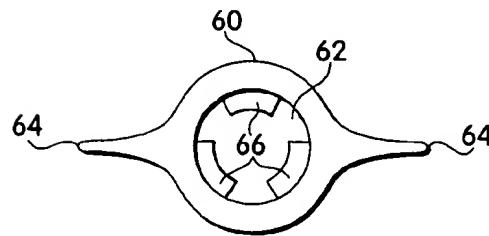


Fig. 6

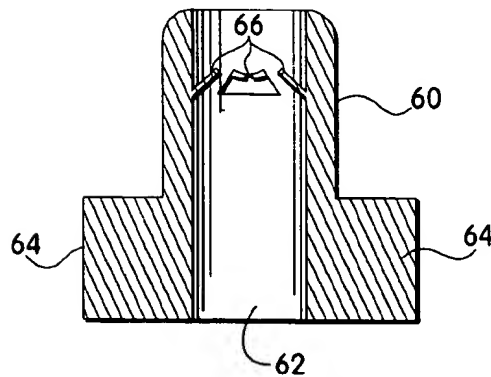


Fig. 7

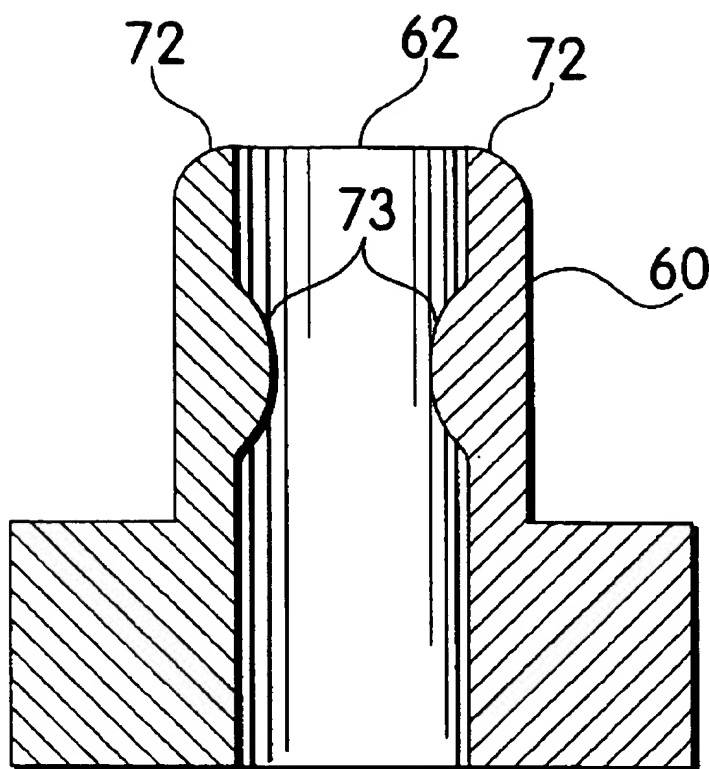


Fig. 8

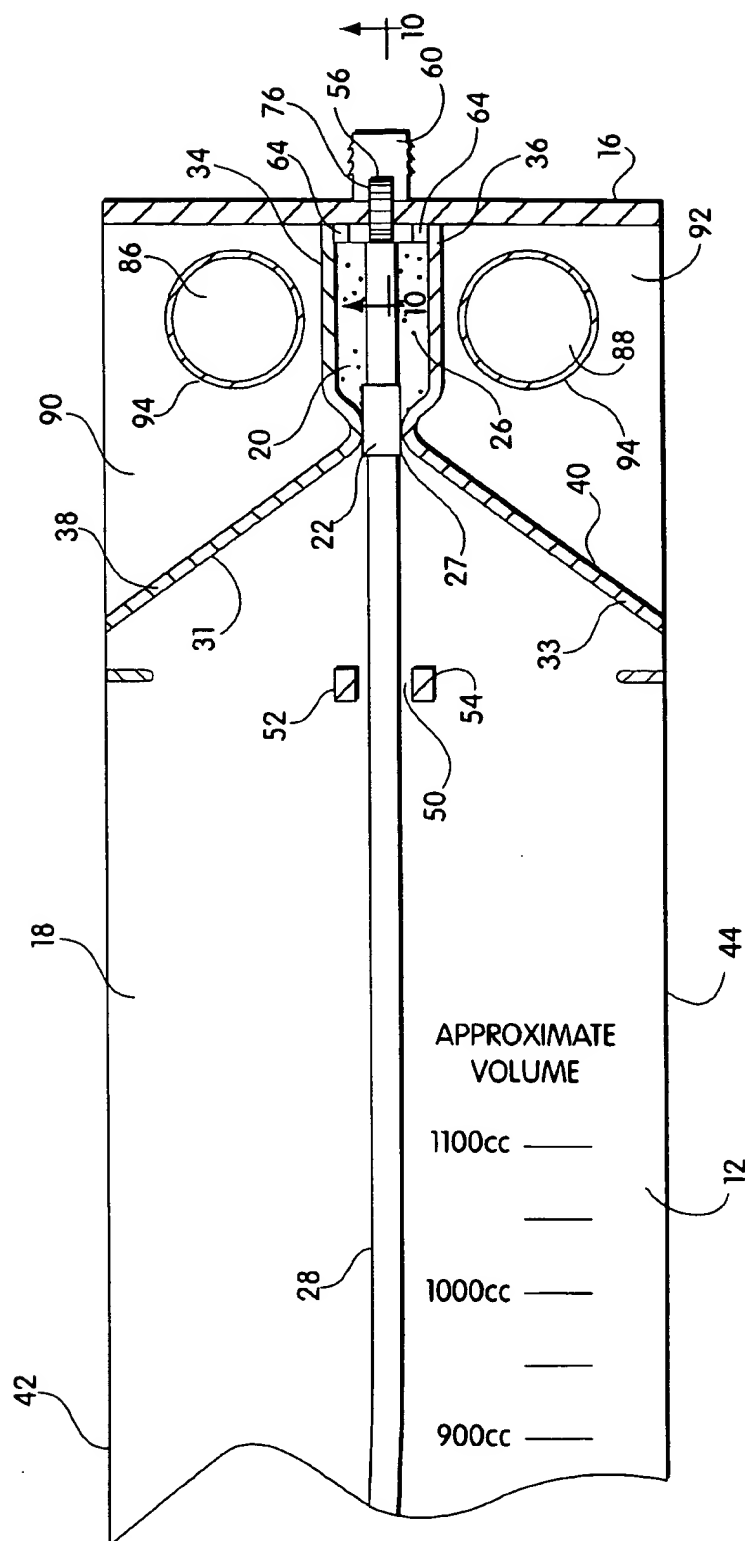


Fig. 9



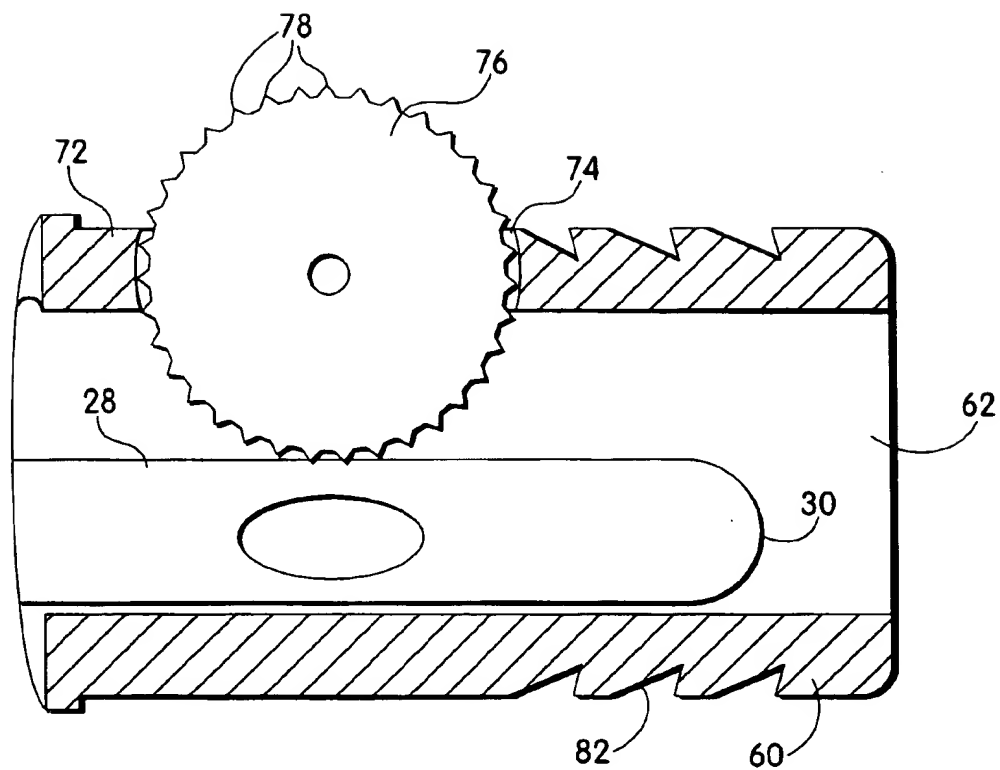


Fig. 10

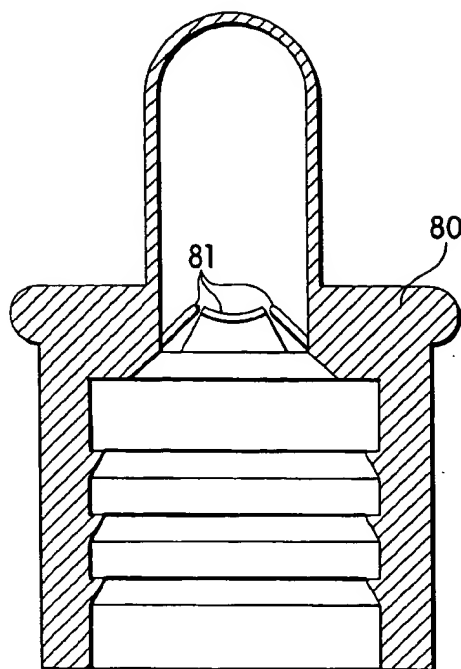


Fig. 11

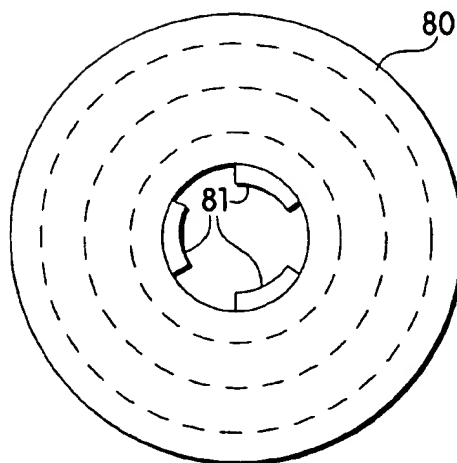


Fig. 12

# SELF CONTAINED URETHRAL CATHETER ASSEMBLY WITH LUBRICATING CHAMBER

## BACKGROUND OF THE INVENTION

Pre-lubricated, self-contained urinary catheters are useful to provide a cleaner, less time consuming procedure. Catheter handling is reduced, as well as the risk of infection. Generally, self-contained catheters are contained within a flexible receptacle which serves to store the catheter before use and collects the urine during use of the catheter. An introducer, provided at an exit of the receptacle, aids introduction of the catheter into the urethra. The catheter is precoated with a lubricant, which eliminates the need for manual lubrication of the catheter by a user and, since the lubricated catheter is contained within the receptacle until use, incidental contact between the lubricant and the user is minimized.

In use, the distal end of the catheter is introduced into the urethra using the introducer. The catheter is advanced by gripping the catheter through the receptacle and moving the catheter with one hand until the hand reaches the top of the receptacle. The catheter is held in this position with the other hand while the receptacle is straightened out. Then the catheter is advanced another distance. The user proceeds in this manner until the catheter reaches the bladder and urine starts to flow.

A disadvantage of such a prelubricated, self-contained catheter is that the lubricant can become dispersed over the interior of the receptacle, causing the walls of the receptacle to stick together. This can make it difficult to advance the catheter and wastes lubricant. Additionally, it can be difficult to hold the receptacle and guide the catheter at the same time, particularly if a patient is attempting self-catheterization.

## BRIEF SUMMARY OF THE INVENTION

The present invention provides a self-contained, self-lubricating catheter assembly having a receptacle containing a catheter. The receptacle is formed of two opposed flexible walls extending from a distal end to a proximal end. A main chamber and a lubrication chamber are formed between the flexible walls. A passage separates the main chamber and the lubrication chamber, and an exit from the lubrication chamber is formed in the distal end of the receptacle. A lubricating material or lubricant is provided in the lubrication chamber. As the catheter is advanced through the lubrication chamber, it picks up lubricant.

A catheter grasping mechanism is located proximate to and preferably within the exit. The catheter grasping mechanism has a passageway therethrough sized to allow the catheter to pass through. The user can grasp and hold the catheter by squeezing the grasping mechanism with the fingers to retain the catheter in an advanced position. Alternatively, a catheter engaging device may extend partially into the passageway of the grasping mechanism and be configured to permit advancement of the catheter out of the receptacle and resist movement of the catheter back into the receptacle. For example, the catheter engaging device may comprise tabs extending radially inwardly and distally from walls of the passageway. Inwardly extending protrusions or a user-accessible dial with external teeth to engage the catheter may also be provided.

The receptacle may also include one or more finger holes extending therethrough to allow the user to retain the receptacle on one or more fingers, thereby freeing the hand

to more easily position the receptacle adjacent to the opening of the urethra while advancing the catheter.

In use, the user grips the catheter through the receptacle walls and directs it through the lubrication chamber and out the exit. The catheter is advanced by pushing it from the proximal end of the lubrication chamber. When the proximal end of the lubrication chamber reaches the distal end, the user grasps the catheter through the grasping mechanism, lubrication chamber or introducer with a free hand to retain the catheter in the advanced position and straightens out the receptacle with the other hand. Once the receptacle has been straightened out, the user grips the catheter through the walls of the receptacle again and advances it another distance in the same manner.

In this way, the catheter assembly is readily held and used. The lubricant is not smeared within the main chamber of the receptacle. Thus, the walls in the main chamber of the receptacle do not stick together, and the catheter can be more readily gripped and advanced through the walls. Also, less lubricant is wasted. The finger holes allow a user to more readily position the receptacle and retain and guide the catheter at the same time, which is particularly useful for patients who must catheterize themselves.

## BRIEF DESCRIPTION OF THE DRAWINGS

The invention will be more fully understood from the following detailed description taken in conjunction with the accompanying drawings in which:

FIG. 1 is a schematic exploded view of a catheter assembly according to the present invention;

FIG. 2 is a side view of a catheter grasping mechanism according to the present invention;

FIG. 3 is a plan view of the catheter grasping mechanism of FIG. 2;

FIG. 4 is a cross-sectional view of the catheter grasping mechanism of FIG. 2;

FIG. 5 is a side view of a further embodiment of a catheter grasping mechanism according to the present invention;

FIG. 6 is a plan view of the catheter grasping mechanism of FIG. 5;

FIG. 7 is a cross-sectional view of the catheter grasping mechanism of FIG. 5;

FIG. 8 is a cross-sectional view of a further embodiment of a catheter grasping mechanism;

FIG. 9 is a partial plan view of a catheter assembly illustrating a further embodiment of a catheter grasping mechanism;

FIG. 10 is a cross-sectional view taken along lines A—A of FIG. 9;

FIG. 11 is a side view of a further embodiment of a catheter grasping mechanism; and

FIG. 12 is a plan view of the catheter grasping mechanism of FIG. 11.

## DETAILED DESCRIPTION OF THE INVENTION

Referring to FIG. 1, a catheter assembly 10 according to the present invention includes a receptacle 12 having flexible walls made from an extruded or sheet material and extending from a proximal end 14 to a distal end 16. The receptacle includes a main chamber 18 adjacent the proximal end 14 and a lubrication chamber 20 adjacent the distal end 16 of the receptacle 12. A passage 22 separates the lubrication chamber 20 from the main chamber 18. A distal

opening 24 from the lubrication chamber 20 forms an exit in the distal end 16 of the receptacle 12.

The lubrication chamber 20 contains a lubricating gel or lubricant 26. Any suitable medical lubricating gel known in the art can be used. The passage 22 between the lubrication chamber 20 and the main chamber 18 is sufficiently narrow to minimize migration of the lubricant into the main chamber. In an alternative embodiment, a valve assembly 27, shown in FIG. 9, can be located within the passage 22 to further minimize migration of the lubricant.

A catheter 28 is disposed within the receptacle 12. The catheter is typically either a red rubber or a vinyl catheter, as is known in the art. During storage, the catheter is retained in the main chamber 18. During use, a user grasps the catheter through the flexible walls of the receptacle and threads the distal end 30 (see FIG. 10) of the catheter 28 through the passage 22 into the lubrication chamber 20 and out the exit 24. The proximal end 32 of the catheter may be widened or may include a retention device thereon to prevent the catheter from being pulled entirely out of the main chamber.

In the embodiment illustrated in FIG. 1, the receptacle 12 is formed from an extruded material such as a polyethylene which is supplied as a tube cut to a suitable length and sealed at the proximal and distal ends 14, 16. Alternatively, the receptacle could be formed of one or more sheets of a flexible material sealed along seams extending between the proximal and distal ends. The seals at the proximal and distal ends and the seams extending between the ends may be formed in any suitable manner, such as by heat sealing, adhesive, stitching, RF welding, impulse welding, or chemical bonding. Other embodiments are possible. For example, a sheet of a flexible material could be folded to form the proximal end 14 and sealed at the distal end and along sides extending between the proximal and distal ends.

The lubrication chamber 20 and the distal end of the main chamber are defined by bond lines 31, 33 which seal opposed walls of the receptacle together. The lubrication chamber is formed by the bond line portions 34, 36 of bond lines 31, 33 respectively extending generally parallel from the distal end 16 of the receptacle 12. The bond lines converge at the proximal end of the lubrication chamber 20 to define the passage 22 between the lubrication chamber 20 and the main chamber 18. Bond line portions 38, 40 of bond lines 31, 33 respectively then diverge from the passage 22 toward the sides 42, 44 of the receptacle to form the distal end of the main chamber.

Preferably the diverging bond line portions 38, 40 extend at an acute angle from the passage 22 toward the sides 42, 44 of the receptacle 12 to form a catheter guideway as illustrated in FIGS. 1 and 9. This angle aids the user in guiding the distal end 30 of the catheter 28 toward the passage 22 to the lubrication chamber 20. However, the diverging bond line portions 38, 40 may also extend directly toward the sides 42, 44, i.e., parallel to the proximal and distal ends 14, 16 of the receptacle, if desired.

Preferably, a catheter guide channel 50 is also provided in the main chamber, which also functions as a catheter guideway. The guide channel is formed by a pair of short parallel bond lines 52, 54 sealing the opposed walls of the receptacle in a central region of the main chamber 18 and spaced from the passage 22 to the lubrication chamber 20. The guide channel 50 aids in locating the catheter 28 centrally within the main chamber, which is helpful when the user is directing the catheter into and through the lubrication chamber. The guide channel can also be used to hold the catheter

outside of the lubrication chamber 20 prior to using the catheter. The bond lines defining the lubrication chamber, the distal end of the main chamber, and the catheter guide channel can be formed in any suitable manner, such as by heat sealing, adhesive, stitching, RF welding, or impulse welding. In an alternative embodiment, the lubrication chamber can be provided as a separate component, such as a suitably sized bag or bladder sealed within the receptacle adjacent the exit 24; an opening on one end of the bag defines the passage 22 from the main chamber and another opening is located adjacent the exit 24.

A catheter grasping mechanism 56 is located proximate and preferably within the exit 24 from the lubrication chamber 20 to permit advancement of the catheter 28 out of the receptacle 12 and resist slippage of the catheter back into the receptacle. Referring to FIGS. 2-4, the grasping mechanism comprises an insert 60 having a passageway 62 there-through. The insert is fixedly located within the exit 24 in any suitable manner. For example, the insert may include flanges or wings 64 protruding from opposed sides thereof and which are fixed, such as by heat sealing, within the bond line portions 34, 36 at the distal end of the lubrication chamber and within the bond line at the distal end 16 of the receptacle. Preferably, the insert is formed of the same material as the receptacle (for example, polyethylene) to assist in bonding thereto. The insert may be fixed proximate the exit of the receptacle in any other suitable manner, as would be known in the art. Preferably, the protrusion of the insert into the lubrication chamber is minimized to provide additional space for the lubricant therein. In use, the user can grasp and hold the catheter by squeezing the grasping mechanism with the fingers to retain the catheter in an advanced position or by squeezing the catheter through the lubrication chamber.

In another embodiment, illustrated in FIGS. 5-7, the catheter grasping mechanism also includes tabs 66 which extend radially inwardly from walls of the passageway 62 and distally toward the exit 68 of the passageway through the insert. When the catheter is passed through the insert in the direction indicated by arrow 70, the ends of the tabs 66 abut the catheter to frictionally engage the catheter to resist movement back into the receptacle. Although three tabs are shown in the figures, any suitable number can be provided.

In another embodiment, illustrated in FIG. 8, the walls 72 of the passageway 62 of the insert 60 are textured to provide a roughness which frictionally engages the catheter. The texture may comprise an all-over pattern or discrete protrusions 73 extending inwardly from walls of the passageway.

In a further embodiment of the catheter grasping mechanism, illustrated in FIGS. 9 and 10, a slot or aperture 74 is formed through the wall 72 of the insert 60. A dial or gear 76 having outwardly extending teeth 78 is rotatably mounted in the slot in the insert. The dial protrudes through the slot to extend into the passageway 62 in the insert a distance sufficient to frictionally engage the teeth against the catheter. The dial also protrudes outside the insert, where a user's finger can rotate the dial to advance the catheter.

As illustrated in FIG. 1, an introducer 80 to assist insertion of the catheter into the urethra may be placed over the insert 60, as is known in the art. The outer surface 82 of the insert 60 may be ribbed or otherwise textured to assist in frictionally retaining the introducer thereon (see particularly FIG. 10). A cap or cover 84 may be placed over the introducer during storage, also as known in the art. In another embodiment shown in FIGS. 11-12, a catheter grasping mechanism having tabs 81 or other protrusions such as described above

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with respect to the embodiments illustrated in FIGS. 5-8 can be formed within the introducer 80. Alternatively, the catheter can be grasped through the introducer by the user's fingers squeezing the introducer.

Finger holes 86, 88 are provided in the regions 90, 92 of the receptacle 12 adjacent the sides of the lubrication chamber 20. Preferably, one finger hole is provided in each side. The circumference of each finger hole may be reinforced in any suitable manner, such as by a bond line 94, which may be formed as the bond lines described above. The finger holes are particularly useful for self-catheterization. Although two finger holes are shown, it will be appreciated that a single finger hole or three or more finger holes could be provided if desired. Similarly, one or more finger holes can be provided in a receptacle that does not also include the lubrication chamber of the present invention.

In use, the user places a finger of one hand through each hole 86, 88 to suspend the receptacle 12. The remaining fingers of that hand can be used to hold the receptacle adjacent to the urethral opening. The other hand is free to manipulate the catheter 28 within the receptacle. The user grips the catheter through the flexible walls of the receptacle and threads the distal end 30 of the catheter through the passage 22 into the lubrication chamber 20 and out the exit 24.

In the lubrication chamber 20, the outer surface of the catheter 28 picks up a sufficient amount of lubricant 26 to ease insertion of the catheter into the urethra. By retaining the lubricant within the lubrication chamber separate from the main chamber, the walls of the receptacle do not stick together and it becomes easier for the user to manipulate the catheter through the receptacle walls.

Catheter advancement is achieved by gripping the catheter with a first hand through the receptacle walls and pushing it from the proximal end of the lubrication chamber. When the proximal end of the lubrication chamber reaches the distal end, the user releases the catheter. The user can retain the catheter in the advanced position by squeezing the catheter through the catheter grasping mechanism with the fingers of the other hand. The user can employ the fingers which extend through the two finger holes for this purpose. Alternatively, the catheter can be retained in the advanced position by the catheter engaging mechanism described above. The user then straightens out the receptacle with the first hand. Once the receptacle has been straightened out, the user grips the catheter through the walls of the receptacle again and advances it another distance until the proximal end of the lubrication chamber reaches the distal end. Additionally, compressing the lubrication chamber with each advance of the catheter acts as a pumping mechanism to force lubricant through the exit with the catheter. Once the distal end of the catheter reaches the patient's bladder, urine begins to flow and is collected in the main chamber of the receptacle.

Typically, the receptacle can hold up to 1200 cc of liquid, although receptacles having larger or smaller volumes can be provided. Indicia indicating the volume of urine collected may be marked along a wall of the receptacle. The catheter assembly of the present invention is applicable to all sizes of catheters, from 6 to 26 French, and can be used for adults, children, males, and females.

The invention is not to be limited by what has been particularly shown and described, except as indicated by the appended claims.

We claim:

1. A self-contained, self-lubricating catheter assembly comprising:

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a receptacle comprising two opposed flexible, sheet-like walls extending from a closed distal end to a proximal end, a main chamber and a lubrication chamber formed between the flexible, sheet-like walls, a passage separating the main chamber and the lubrication chamber, and an exit from the lubrication chamber formed in the closed distal end of the walls of the receptacle;

a lubricating material disposed in the lubrication chamber; and

a catheter disposed within the receptacle.

2. The catheter assembly of claim 1, wherein the passage between the lubrication chamber and the main chamber is sufficiently large to allow a catheter to pass therethrough and sufficiently narrow to minimize migration of the lubricating material from the lubrication chamber into the main chamber.

3. The catheter assembly of claim 1, wherein the receptacle further includes a catheter guideway disposed to direct the catheter toward the lubrication chamber.

4. The catheter assembly of claim 3, wherein the catheter guideway comprises a guide channel formed in a central region of the main chamber spaced from the lubrication chamber.

5. The catheter assembly of claim 1, further comprising a catheter grasping mechanism located within the exit, the catheter grasping mechanism having a passageway therethrough sized to allow the catheter to pass through.

6. The catheter assembly of claim 5, further comprising a catheter engaging device extending partially into the passageway and configured to permit advancement of the catheter out of the receptacle and resist movement of the catheter back into the receptacle.

7. The catheter assembly of claim 6, wherein the catheter engaging device comprises tabs extending radially inwardly and distally from walls of the passageway.

8. The catheter assembly of claim 6, wherein the catheter engaging device comprises protrusions extending inwardly from walls of the passageway.

9. The catheter assembly of claim 6, wherein the catheter engaging device comprises a dial rotatably mounted within an aperture in the catheter grasping mechanism, the dial having outwardly extending teeth disposed to protrude within the passageway to frictionally engage against the catheter and to extend outside the aperture for access by a user's finger.

10. The catheter assembly of claim 5, further comprising an introducer disposed over the catheter grasping mechanism.

11. The catheter assembly of claim 10, further comprising a cap disposed over the catheter grasping mechanism.

12. The catheter assembly of claim 10, further comprising a catheter engaging device extending partially into the introducer and configured to permit advancement of the catheter out of the receptacle and resist movement of the catheter back into the receptacle.

13. The catheter assembly of claim 1, further comprising a valve assembly disposed in the passage between the lubrication chamber and the main chamber.

14. A self-contained, self-lubricating catheter assembly comprising:

a receptacle comprising two opposed flexible walls extending from a closed distal end to a proximal end, a main chamber and a lubrication chamber formed between the flexible walls, a passage separating the main chamber and the lubrication chamber, and an exit from the lubrication chamber formed in the closed distal end of the receptacle, wherein the lubrication

chamber is formed by bond lines sealing the opposed flexible walls;  
 a lubricating material disposed in the lubrication chamber;  
 and

a catheter disposed within the receptacle.

15. The catheter assembly of claim 14, wherein the bond lines are formed by heat sealing, adhesive, stitching, RF welding, impulse welding, or chemical bonding.

16. A self-contained, self-lubricating catheter assembly comprising:

a receptacle comprising two opposed flexible walls extending from a closed distal end to a proximal end, a main chamber and a lubrication chamber formed between the flexible walls, a passage separating the main chamber and the lubrication chamber, and an exit from the lubrication chamber formed in the closed distal end of the receptacle;

a lubricating material disposed in the lubrication chamber;  
 a catheter disposed within the receptacle; and

a catheter guideway disposed to direct the catheter toward the lubrication chamber, the guideway comprising a guide channel formed in a central region of the main chamber spaced from the lubrication chamber, wherein the guide channel is formed by bond lines sealing the opposed flexible walls.

17. A self-contained, self-lubricating catheter assembly comprising:

a receptacle comprising two opposed flexible walls extending from a closed distal end to a proximal end, a main chamber and a lubrication chamber formed between the flexible walls, a passage separating the main chamber and the lubrication chamber, and an exit from the lubrication chamber formed in the closed distal end of the receptacle;

a lubricating material disposed in the lubrication chamber and

a catheter disposed within the receptacle; and

a catheter guideway disposed to direct the catheter toward the lubrication chamber, wherein the catheter guideway comprises bond lines sealing the opposed flexible walls and extending angularly from the lubrication chamber to sides of the receptacle.

18. A self-contained, self-lubricating catheter assembly comprising:

a receptacle comprising two opposed flexible walls extending from a distal end to a proximal end, a main chamber and a lubrication chamber formed between the flexible walls, a passage separating the main chamber and the lubrication chamber, and an exit from the lubrication chamber formed in the distal end of the receptacle;

a lubricating material disposed in the lubrication chamber;  
 a catheter disposed within the receptacle; and

a finger hole disposed through the opposed flexible walls in a region adjacent to the distal end and on a side of the lubrication chamber.

19. The catheter assembly of claim 18, further comprising a further finger hole disposed through the opposed flexible walls in a further region adjacent the distal end and on an opposite side of the lubrication chamber from the finger hole.

20. The catheter assembly of claim 18, further comprising reinforcing around the finger opening.

21. The catheter assembly of claim 20, wherein the reinforcing comprises a bond line around the finger opening.

22. A self-contained catheter assembly comprising:

a receptacle comprising two opposed flexible walls extending from a proximal end to a distal end, and a chamber between the flexible walls;

a catheter, at least a portion of the catheter disposed within the chamber in the receptacle;

an exit formed in the distal end of the walls of the receptacle; and

a catheter grasping mechanism located within the exit, the catheter grasping mechanism having a passageway therethrough sized to allow the catheter to pass through and operative to retain the catheter therein, and including a catheter engaging device extending partially into the passageway to permit advancement of the catheter out of the receptacle and resist movement of the catheter back into the receptacle.

23. The catheter assembly of claim 22, wherein the catheter engaging device comprises protrusions extending inwardly from walls of the passageway.

24. The catheter assembly of claim 22, wherein the catheter engaging device comprises tabs extending radially inwardly and distally from walls of the passageway.

25. The catheter assembly of claim 22, wherein the catheter grasping mechanism is sufficiently squeezable to allow the catheter to be retained therein by squeezing of a user's fingers.

26. The catheter assembly of claim 22, further comprising an introducer disposed over the catheter grasping mechanism.

27. The catheter assembly of claim 26, further comprising a cap disposed over the introducer.

28. A self contained catheter assembly comprising:

a receptacle comprising two opposed flexible walls extending from a proximal end to a distal end, and a chamber between the flexible walls;

a catheter, at least a portion of the catheter disposed within the chamber in the receptacle;

an exit formed in the distal end of the receptacle;

a catheter grasping mechanism located within the exit, the catheter grasping mechanism having a passageway therethrough sized to allow the catheter to pass through and including a catheter engaging device extending partially into the passageway, wherein the catheter engaging device comprises a dial rotatably mounted within an aperture in the catheter grasping mechanism and configured to permit advancement of the catheter out of the receptacle and resist movement of the catheter back into the receptacle, the dial having outwardly extending teeth disposed to protrude within the passageway to frictionally engage against the catheter and to extend outside the aperture for access by a user's finger.

29. A self-contained catheter assembly comprising:

a receptacle comprising two opposed flexible walls extending from a proximal end to a sealed distal end, and a chamber between the flexible walls, wherein the chamber comprises a main chamber and a lubrication chamber defined by bond lines sealing the opposed flexible walls, and a lubricating material is disposed in the lubrication chamber;

a catheter, at least a portion of the catheter disposed within the chamber in the receptacle;

an exit formed in the distal end of the receptacle; and

a catheter grasping mechanism located within the exit and fixed to the sealed distal end, the catheter grasping

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mechanism having a passageway therethrough sized to allow the catheter to pass through and operative to retain the catheter therein.

30. A self-contained catheter assembly comprising:

a receptacle comprising two opposed flexible walls extending from a proximal end to a distal end, and a chamber between the flexible walls, the opposed walls comprising a further portion adjacent to the chamber and the distal end, and a finger hole disposed through the further portion of the opposed walls;

a catheter, at least a portion of the catheter disposed within the chamber in the receptacle;

an exit formed in the distal end of the receptacle; and

a catheter grasping mechanism located within the exit, the catheter grasping mechanism having a passageway therethrough sized to allow the catheter to pass through and operative to retain the catheter therein.

31. A prelubricated, self-contained catheter assembly comprising:

a receptacle having two opposed flexible walls extending from a proximal end to a distal end, a chamber defined between a portion of the opposed walls, at least a further portion of the opposed walls adjacent the chamber, at least one finger hole disposed through the further portion of the opposed walls;

an exit from the chamber formed in the distal end of the receptacle; and

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a catheter, at least a portion of the catheter disposed within the receptacle.

32. The catheter assembly of claim 31, wherein the chamber is defined by bond lines sealing the opposed flexible walls.

33. The catheter assembly of claim 31, wherein the chamber comprises a main chamber and a lubrication chamber defined by bond lines sealing the opposed flexible walls, and a lubricating material disposed in the lubrication chamber.

34. The catheter assembly of claim 31, further comprising two finger holes disposed on opposed sides of the lubrication chamber.

35. The catheter assembly of claim 31, further comprising reinforcing around the finger opening.

36. The catheter assembly of claim 35, wherein the reinforcing comprises a bond line around the finger opening.

37. The catheter assembly of claim 31, further comprising a catheter grasping mechanism located proximate the exit, the catheter grasping mechanism having a passageway therethrough sized to allow the catheter to pass through.

38. The catheter assembly of claim 37, further comprising a catheter engaging device extending partially into the passageway and configured to permit advancement of the catheter out of the receptacle and resist movement of the catheter back into the receptacle.

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